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A Decline in HIV-Infected Needles Returned to New Haven's Needle Exchange Program: Client Shift or Needle Exchange?

Edward H. Kaplan, PhD, Kaveh Khoshnood, MPH, and Robert Heimer, PhD

ABSTRACT

The New Haven needle exchange program experienced a significant decline in the fraction of returned needles containing human immunodeficiency virus 1 (HIV-1) proviral DNA. Is this decline due to the operations of the needle exchange or to a shift in clients? Analysis of demographic and behavioral data revealed that only one variable, the race of participating clients, changed significantly over time. However, HIV-1 prevalences in needles given to Whites and to non-Whites were not statistically different. Thus, client shift cannot be responsible for the decline in the observed HIV prevalence in needles. Instead, needle circulation times were a significant predictor of HIV prevalence. (*Am J Public Health.* 1994;84:1991–1994)

Introduction

The New Haven Department of Health has operated a legal needle exchange program since November 13, 1990. The program has been evaluated by using data collected via a syringe-tracking and testing system.[1,2] We previously reported that the fraction of returned syringes containing human immunodeficiency virus 1 (HIV-1) proviral DNA fell significantly.[3,4] Our prior research elaborated a circulation theory, which holds that program operations account for this decrease.[2,5] This theory posits that as clients visit the exchange more frequently, the time needles remain in circulation decreases, lessening the opportunities for needles to share people! As a consequence, needles have a lower probability of becoming infected, and those sharing needles have a lower risk of infection. The question is, does decreasing circulation time explain the fall in the fraction of positive syringes, or is some other factor responsible for the observed decline?

An explanation for the decrease in the fraction of positive syringes that competes with the circulation theory is the client shift hypothesis, which posits that program participants have changed over time, from a group with high risk of HIV infection to a group with lower risk. Because direct serological testing of program participants was forbidden by program administrators, our approach to testing this hypothesis relied on identifying injectors at higher risk for HIV infection. Decreased program participation by this group could produce a drop in the frequency of positive findings among

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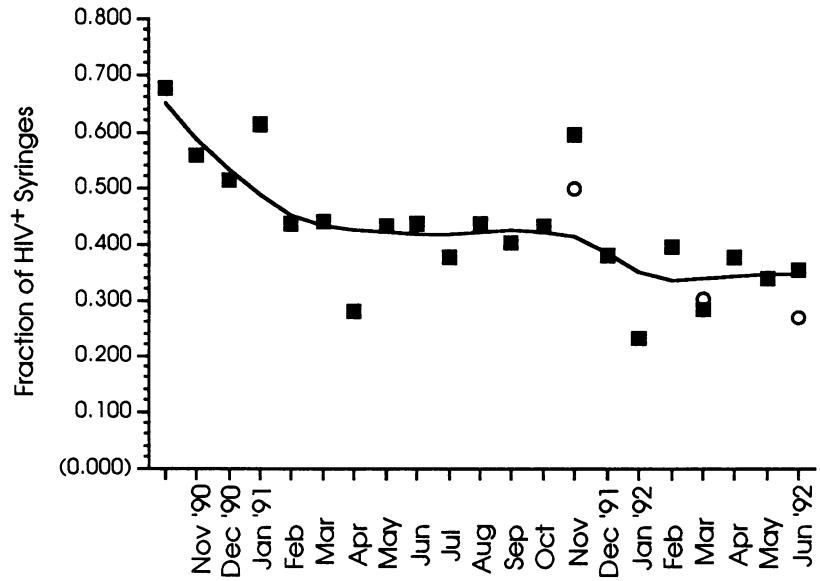

Note. Syringes were tested for the presence of HIV-1 proviral DNA by PCR (■) or for the presence of antibodies to HIV-1 by EIA (○). At the start of the program, 160 of the first 650 returned syringes were tested by PCR; the 67.5% that were positive appear as the first point on the graph. In November 1990, the first half-month of program operations, 52 syringes distributed by and returned to the program were tested. Thereafter, at least 90 syringes distributed by and returned to the program were tested per month by PCR. The curve is a smoothing of the HIV prevalence data with the 4253H, twice algorithm.[17] The reliability of the PCR data was supported by EIA testing of at least 135 syringes distributed by and returned to the program in each of 3 months (November 1991, March 1992, and June 1992), which produced data entirely consistent with that found by using PCR. PCR = polymerase chain reaction; EIA = enzyme immunoassay.

FIGURE 1—Testing syringes for use by drug injectors infected with HIV-1.

TABLE 1—Multivariate Analysis of Variance on Self-Reported Demographic and Behavioral Variables

Statistic	Value	*P*
All variables except cleaning (sample size = 3925 person-months)		
Wilks' lambda	0.9471	.0009
Pillai's trace	0.0537	.0011
Hotelling-Lawley trace	0.0551	.0007
All variables except cleaning and race (sample size = 3935 person-months)		
Wilks' lambda	0.9663	.4473
Pillai's trace	0.0341	.4559
Hotelling-Lawley trace	0.0345	.4388

the tested needles. This hypothesis, if verified empirically, would suggest that the operation of needle exchange in itself may not reduce HIV transmission risks. As the client shift hypothesis formalizes one of the major criticisms of needle exchange programs,[6] it should be examined carefully.

Methods

The study populations include participants in the New Haven needle exchange and their syringes. The study period began concomitantly with program operations in November 1990 and continued through June 1992, when the state criminal statute on possession and sale of syringes without a prescription was repealed.

One source of data was the returned syringes. Of the 30 429 syringes distributed by and returned to the program, 2813 were selected for testing in a two-staged systematic sampling process. To guarantee representation of the entire client population, in the first stage of the procedure we selected all syringes returned from batches of one or two, and two syringes from batches of three or more. Residual blood from these syringes was extracted with a nonionic detergent solution.[7] Thus, all clients contributed syringes in the first sampling stage from which extracts were prepared, but we increased the likelihood of sampling from those who exchange fewer syringes, broadening our view of the total program population. In the second stage, every 10th extract was selected for testing with "nested" polymerase chain reaction, which permits detection of a single copy of HIV-1 proviral DNA.[7,8] After the polymerase chain reaction, we detected HIV-specific DNA using gel electrophoresis and Southern blotting with an HIV-1 specific probe. False-positive results, the bugbear of polymerase chain reaction technology, were avoided by inclusion of a large battery of true negative controls. Results of polymerase chain reaction testing were corroborated with an antibody-based HIV detection assay (Abbott Laboratories HIV-1 viral-based enzyme immunoassay).[8,9] A second source of data was self-reported behavioral and demographic variables collected at client enrollment. Clients who visited the program three or more times contributed the overwhelming majority of tested needles, and only these clients were included in this analysis. The data were exploded to form a time series by considering which clients were participating in each of the 20 months under analysis. A third source of data was the syringe-tracking system, which details the dates, location, and client identification codes of distributed and returned needles. These data enabled compilation of needle circulation times.[5]

The client shift hypothesis was tested by multivariate analysis of variance (MANOVA) to determine whether nine self-reported variables remained stable over time. The variables were sex of client, age at enrollment, duration of drug injection, daily frequency of injection, fraction of time injecting in shooting galleries, fraction of time injecting with shared equipment, fraction of time cleaning injection equipment, injected cocaine (yes or no), and race (White or non-White). They were selected because of their association with an increased likelihood of HIV infection among injection drug users in the northeastern United States.[10–16] The specific null hypothesis tested was that these variables remained simultaneously stable over the 20 months under study. Circulation theory, which posits that the prevalence of HIV-positive needles increases with needle circulation time, was tested with logistic regression models.

TABLE 2—Logistic Regressions Predicting Monthly Syringe HIV Prevalence

Model	Variable	Coefficient	Standard Error	*t* Ratio
Race alone[a]	Constant	−0.3976	0.0680	−5.85
	Race	0.0733	0.0828	0.89
Circulation time alone[b]	Constant	−0.7029	0.0901	−7.80
	Circulation time	0.1150	0.0263	4.37
Circulation time and race[c]	Constant	−0.6886	0.0825	−4.56
	Circulation time	0.0801	0.0370	2.16
	Race	−0.1574	0.1939	−0.81
	Circulation time/race interaction	0.1055	0.0543	1.94

[a] $\chi^2 = 0.78$; 1 df; log likelihood = −1850.42; not significant.
[b] $\chi^2 = 19.43$; 1 df; log likelihood = −1841.10; $P < .0001$.
[c] $\chi^2 = 27.61$; 3 df; log likelihood = −1837.00; $P < .0001$.

Results

Polymerase chain reaction testing on 2813 returned program syringes revealed that 1163 (or 41.3%) contained HIV-1 specific DNA. The percentage of positive tests, initially exceeding 60%, decreased to less than 45% within 5 months and remained at or below that level (Figure 1). In 3 of the months in the study period, we tested syringes for the presence of anti-HIV-1 antibodies, finding results entirely consistent with polymerase chain reaction testing (Figure 1).

MANOVA results on the nine variables produced *P* values of greater than 0.35 for all three test statistics. However, this analysis was based on 2814 client-months (59% of the full data set) because in 1507 client-months a value for cleaning frequency was missing. To broaden our database we performed the MANOVA excluding cleaning frequency, thereby increasing our sample size to 96% of the maximum. The MANOVA with eight variables revealed that all three test statistics were now significant, with *P* values of less than 0.0015 (Table 1). A variable-by-variable analysis showed that only race had changed significantly, as the fraction of Whites had increased over time. This consideration was formalized by MANOVA on variables excluding race and cleaning frequency. The three tests for profile stability all report *P* values of greater than 0.40 (Table 1), prohibiting the rejection of the null hypothesis. Thus, only the race of program clients changed significantly over time.

Could the change in the racial composition of the client population explain the decrease in the fraction of syringes testing positive? To explore this possibility, we first examined the monthly prevalence in syringes given to White and non-White clients over the 20-month study period. With Whites coded as zero and non-Whites as one, logistic regression analyses are displayed in Table 2. No significant difference in HIV prevalence by race was detected ($\chi^2 = 0.78$, not significant). Alternatively, mean needle circulation time proved significant, with increasing circulation time predicting increasing HIV prevalence in syringes ($\chi^2 = 19.43, P < .0001$). Considering race, circulation time, and their interaction again revealed circulation time as a significant predictor, whereas race alone failed to achieve significance, and the interaction was marginally significant ($\chi^2 = 27.61, P < .0001$).

Discussion

Evaluation of the New Haven needle exchange program relied on the development of a syringe-tracking and testing system that detected a large decrease in the fraction of syringes used by individuals infected with HIV-1. Could this decrease be attributed to something other than the program's ability to decrease the circulation time of distributed syringes? A competing hypothesis, client shift, cannot explain the decrease. Of the demographic and behavioral variables investigated, only race was found to vary significantly during the period under study. However, on comparing the HIV prevalence in needles given to White and non-White clients, no significant difference was found. Instead, we found that mean needle circulation time significantly predicted the level of HIV-positive needles, with increasing circulation time corresponding to increasing HIV prevalence in needles. This prevalence declined over time both in needles distributed to Whites and in needles distributed to non-Whites, along with a decrease in mean circulation times of needles given to each group. Thus, the only role for race in explaining the observed decline in HIV prevalence in needles is via the differential effect of declining circulation times among needles distributed to each group. These findings strongly support the contention that needle exchange, and not client shift, is responsible for the decline in HIV prevalence in needles returned to the New Haven needle exchange program. □

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Predicting the Effect of the Oregon Health Plan on Medicaid Coverage for Outpatients with HIV

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ABSTRACT

The Oregon Health Plan, which took effect in February 1994, extends Medicaid eligibility but limits coverage to conditions and treatments above a certain threshold on a prioritized list. Retrospective analysis was conducted on records of visits to two Oregon human immunodeficiency virus (HIV) outpatient clinics in 1991 and 1992 to determine Medicaid coverage if the plan had been operational. Of 1129 patients, 21.1% were Medicaid-eligible; an additional 56.5% would have been eligible under the Oregon plan. Only 5.0% to 6.8% of these patients' visits were for conditions listed below the plan's coverage threshold; almost none of these were for HIV-specific conditions. (*Am J Public Health.* 1994;84: 1994–1996)

Introduction

In 1989, the Oregon State Legislature passed three bills establishing the Oregon Health Plan, which was intended to provide access to health care coverage for nearly all state residents. The Medicaid reform component took effect in February 1994 and extends coverage to all state residents with incomes below the federal poverty level.[1] However, in this first attempt in the United States to ration health care explicitly, coverage will not be provided for all health conditions and will be limited to diagnostic visits, preventive care, and health condition–treatment pairs that rank above a certain threshold on a prioritized list. This list was drawn up by the Oregon Health Services Commission during a four-year process[2–10] and bases the location of condition–treatment pairs primarily on the effectiveness of treatment in increasing the probability of survival.[8]

Condition–treatment pairs were also ranked inversely to the average cost of treatment over the lifetime of the condition. The Health Services Commission then adjusted the resulting rankings, raising the rankings for pairs with conditions that pose public health risks or treatments that prevent conditions, additional complications, or future costs. The commission lowered rankings for treatments that do not meet their objectives and assigned condition–treatment pairs for certain types of services to particular regions of the list according to perceived citizen values.[3] The list contains a total of 696 lines; the Oregon legislature, given statutory responsibility for setting the Medicaid coverage threshold, set the threshold below line 565.

Any rationing plan based on treatment effectiveness and cost poses the danger of denying coverage for diseases that are chronic and expensive to treat and that have a poor prognosis and no established standard of care. By all of these criteria, human immunodeficiency virus (HIV) infection appears to be susceptible to denial of coverage. This denial could have serious consequences because many people with HIV lose private insurance and must rely on Medicaid. To predict the impact of Oregon's plan in extending Medicaid eligibility and limiting coverage, we conducted a retrospective study of claims records for outpatient visits made to two large HIV clinics: one in Multnomah County and one at Oregon Health Sciences University in Portland. Both clinics have high proportions of Medicaid and uninsured HIV patients, those most likely to be affected by the plan. Our study examined data from 13 956 outpatient visits made by 1129 patients during 1991 and 1992. Data for each visit—including a patient's insurance coverage, monthly income, family

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